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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,806	01/22/2004	Yuichi Kataishi	NPR-132	2300
20374	7590	04/27/2006		
KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/761,806	Applicant(s) KATAISHI ET AL.	
	Examiner Andrew M. Gilbert	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,11,13,15,17,19,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,11,13,15,17,19,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 4/13/2006.
2. In the reply, claims 2, 4, 6, 12, 14, 16, 18, and 20 have been cancelled.

Additionally, amendments to claims 1, 3, 5, 11, 13, 15, 17, and 19 correspond to claims 2, 4, 6, 12, 14, 16, 18, and 20 respectively, prior to the amendment in the reply. Thus, claims 1, 3, 5, 7, 11, 13, 15, 17, 19, 21, and 22 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 5, 7, 11, 13, 15, 17, 19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al (6152909) in view of Grasso, III et al (6375651), hereafter referred to as Grasso, in further view of Windischman et al (2716983).
5. In reference to claims 1, 3, 7, 15, 17, 19, 21, and 22 Bagaoisan et al discloses an aspiration catheter (210) with a tube with a lumen from the proximal to distal end (214), an insertion port in the catheter apart from the distal end of the catheter (211), a second lumen extending from the insertion port to an opening at the distal end (212), a third lumen (Fig 14) have a reinforcing wire (216a or 216b) that ends at a position apart from the distal end of the catheter (col 11, Ins 18-21), a distal end opening having a cut

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surface angled with respect to the axis of the catheter (212; Fig 13) ending in a surface that is flat and flexible (Fig 13; col 11, lns 43-47) on the necked-down tip at the distal side of the cut surface (Fig 13), the necked-down tip having a second lumen (214) and being eccentric to the longitudinal axis (Fig 13, 14), having a marker (224) for identifying the position of the distal tip in the body, the aspiration pump can provide aspiration pressure in variable and continuous settings at the proximal end of the catheter (col 12; lns 64-66), and the aspiration pump can exceed a suction pressure of 650 mmHg (12.5 psi) while preferably not exceeding 30 psi (col 16, lns 10-15).

6. However, Bagaoisan et al does not disclose a portion of the cut surface on the proximal side being concave in the angled direction. Grasso teaches that it is known to have a cut surface being concave (Fig 2C) in the angled direction for the purpose of have a side opening that provides easier access to target materials being removed along the walls of a blood vessel (col 5, lns 29-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cut surface as taught by Bagaoisan et al with the concave cut surface as taught by Grasso for the purpose of provides easier access to target materials being removed along the walls of a blood vessel.

7. Futhermore, in reference to claims 1, 3, 7, 15, 17, 19, 21, and 22, Bagaoisan et al and Grasso disclose the invention substantially as claimed except for a first cut surface angled in the proximal direction of the catheter, a ledge surface parallel to the longitudinal axis of the catheter extending from the first cut surface in the proximal direction to a second cut surface that is concave and angled in the proximal direction of

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the catheter. Windischman et al teaches that it is known to have a first cut surface angled in the proximal direction of the catheter(7; Fig 3), a ledge surface parallel to the longitudinal axis of the catheter (14; Fig 3) extending from the first cut surface in the proximal direction to a second cut surface that is concave and angled in the proximal direction of the catheter (16; Figs 3, 4) the purpose of providing a distal end opening structure to the lumen that helps prevent the lumen from becoming clogged. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end opening cut surface as taught by Bagaoisan et al and Grasso with the cut surfaces as taught by Windischman et al for the purpose of providing a distal end opening structure to the lumen that helps prevent the suction lumen from becoming clogged.

8. In reference to claim 5, Bagaoisan et al, Grasso, and Windischman et al disclose the invention substantially as claimed except for expressly disclosing that the opening at the distal end of the catheter provides a pressure loss at the start of suction of 90% or less. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a pressure loss at the start of suction of 90% or less because the Applicant has not disclosed that having a pressure loss at the start of suction of 90% or less provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the pressure loss response of the catheter of Bagaoisan et al, Grasso, and Windischman et al because the aspiration catheter performs the same purpose of removing thrombi from

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blood vessels through similar sized lumens and a similar suction source. Therefore, it would have been an obvious matter of design choice to modify Bagaoisan et al, Grasso, and Windischman et al to obtain the invention as specified in claim 5.

9. In reference to claims 11 and 13, Bagaoisan et al, Grasso, and Windischman et al disclose the invention substantially as claimed except for expressly disclosing that the insertion port is provided at a position 25-35 cm from the distal end of the opening of the distal end of the catheter. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the insertion port at a position 25-35 cm from the distal end of the catheter because the Applicant has not disclosed that having the insertion port at a position 25-35 cm from the distal end of the catheter provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the insertion port of Bagaoisan et al, Grasso, and Windischman et al because the insertion port and guidewire lumen has the same purpose of maneuvering the catheter in the body. Therefore, it would have been an obvious matter of design choice to modify Bagaoisan et al and Grasso to obtain the invention as specified in claims 11 and 13.

Response to Arguments

10. Applicant's arguments filed 4/7/2006 have been fully considered but they are not persuasive.

11. The Applicant argues that the 35 U.S.C. 103(a) rejection of claims 2, 4, 6, 12, 14, 16, 18, and 20 in the previous office action (now amended claim 1 and claims 3, 5, 11,

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13, 15, 17, 19, 21, and 22) is improper because the prior art does not support motivation for combining Windischman with Bagaosian and Grasso. The invention of Windischman is a piercing needle, not a catheter and the Office has not shown that a design of a piercing needle to prevent clogging of the needle with a piece of a rubber diaphragm or skin would be reasonably expected by a person of ordinary skill in the art to prevent clogging of a suction catheter as described in Bagaosian (Remarks, pg 9).

12. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the invention of Windischman related to needles for use in the medical arts, such needles being provided with a cannula through which fluid can flow (col 1, lns 15-17). As defined by Webster's Dictionary, a catheter is "a tubular device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open." The piercing needle of Windischman is fully capable of acting as a tubular device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open and therefore can be termed a catheter. The design of the piercing needle end, or catheter end, is designed for the purpose of providing a distal end opening structure to the lumen

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that helps prevent the lumen from becoming clogged to permit fluid flow there through (col 1, Ins 15-17). The distal end opening of the catheter of Bagaoisan has fluid flow there through; hence, the design of the piercing needle end, or catheter end, that helps provide a distal end opening structure to the lumen from becoming clogged and allowing fluid flow there through is in the same problem solving area motivation to modifying the distal end opening of Bagaoisan with the piercing needle end design exists to provide a distal end opening structure to the lumen that helps prevent the lumen from becoming clogged. Thus, the rejection stands.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571)

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272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

KEVIN SIRMONS
PRIMARY EXAMINER

